

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9001

Bartle, J.

February 1, 2013

Mary L. Rhodes ("Ms. Rhodes" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Thomas K. Rhodes, claimant's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Timothy P. Obarski, M.D. Dr. Obarski is no stranger to this litigation. According to the Trust, he has signed in excess of 60 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated June 7, 2002, Dr. Obarski attested in Part II of claimant's Green Form that she suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and an abnormal left

3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1) - (2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

atrial dimension.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$512,025.⁵

In the report of claimant's echocardiogram, Dr. Obarski indicated that claimant had moderate mitral regurgitation with an RJA/LAA ratio of "20-40%." Dr. Obarski, however, did not specify an exact percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA"), in any apical view, is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2005, the Trust forwarded the claim for review by Issam A. Mikati, M.D., one of its auditing cardiologists. In audit, Dr. Mikati concluded that there was no reasonable medical basis for Dr. Obarski's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this

4. Dr. Obarski also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

conclusion, Dr. Mikati explained that "[b]lack pixels were included on one measurement. Bakflow (sic) was measure[d] on another tracing."

Based on Dr. Mikati's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying the claim of Ms. Rhodes. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant argued that she should prevail because there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. In support of this assertion, claimant submitted two subsequent echocardiogram tapes and corresponding reports, which in her view demonstrated that she had moderate mitral regurgitation. In the report of claimant's November 26, 2002 echocardiogram, the reviewing cardiologist, James M. Ronaldson, M.D., stated that claimant had "[m]oderate mitral regurgitation." Dr. Ronaldson, however, did not specify a percentage as to claimant's level of mitral regurgitation. In the report for claimant's February 3, 2004 echocardiogram, the reviewing cardiologist, David Pocoski, M.D., stated that claimant's "mitral regurgitation is physiologically significant

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

but not severe," which claimant asserted "is another way of saying 'moderate.'" Dr. Pocoski also did not specify a percentage as to claimant's level of mitral regurgitation.

The Trust then issued a final post-audit determination, again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On February 13, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5986 (Feb. 13, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 2, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had an opportunity to develop the Show Cause

7. A [Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the Court. The Show Cause Record and Technical Advisor Report are now before the Court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Rhodes reasserts the arguments that she made in contest, namely, that she should prevail because "the attesting physician Dr. Timothy Obarski, a Level III Cleveland clinic trained physician determined that she had moderate mitral regurgitation...." Claimant also asserts that the auditing cardiologist's opinions are "obviously refuted, not only by Dr. Obarski's own findings, but [by] the two subsequent findings of two different cardiologists shortly after

the echocardiogram in question and one year and three months later."

In response, the Trust argues that claimant has failed to establish a reasonable medical basis for her claim because she failed to rebut any of the auditing cardiologist's specific findings as to the level of her mitral regurgitation. The Trust also contends that claimant did not respond to the specific deficiencies identified by the auditing cardiologist and that providing additional echocardiograms cannot provide a reasonable medical basis for her attesting physician's answer regarding claimant's level of regurgitation on the June 2002 echocardiogram.

The Technical Advisor, Dr. Abramson, reviewed claimant's record and echocardiograms and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Rhodes had moderate mitral regurgitation.

Dr. Abramson explained:

The study dated 6/07/02 performed by EchoMotion showed normal left ventricular size and systolic function, abnormal left atrial dimension, and mild mitral regurgitation in all views. There is one tracing of the left atrium (17.23 cm^2) that excludes some of the left atrium thereby resulting in a smaller measurement than the true measurement. There are four tracings of the mitral regurgitant jet. Two of the tracings (3.27 cm^2 and 3.29 cm^2) are accurate resulting in a RJA/LAA ratio <20% despite the too small measurement of the left atrium. The other two measurements (4.95 cm^2 and 4.83 cm^2) are erroneously large because the tracings include black pixels outside the true mitral regurgitation envelope. The

mitral regurgitant jet is early systolic, not holosystolic, which is consistent with mild mitral regurgitation.

I also reviewed the echocardiograms dated 11/26/02 and 2/03/04. The mitral regurgitation on both of these studies also was mild. There is no evidence that the mitral regurgitation on any of these studies was more than mild.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately contest the findings of the auditing cardiologist and the Technical Advisor. Specifically, Dr. Mikati found that the measurements on claimant's echocardiogram included black pixels and backflow. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Rhodes rests only on Dr. Obarski's check-the-box diagnosis on her Green Form.⁸ In addition, Dr. Abramson concluded that LAA tracing on the tape excluded some of the left atrium and that the two largest RJA measurements included black pixels outside the true mitral regurgitation envelope.⁹ Mere disagreement with the auditing cardiologist and a failure to respond to the Technical Advisor are insufficient to meet claimant's burden of proof.

8. As neither of the echocardiograms claimant submitted in contest addresses the specific errors identified by the auditing cardiologist for the echocardiogram upon which claimant's Green Form is based, they do not assist claimant in meeting her burden of proof. In any event, Dr. Abramson found, and claimant did not dispute, that these echocardiograms demonstrated only mild mitral regurgitation.

9. Despite the opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

We also disagree with claimant that there is a reasonable medical basis for Dr. Obarski's finding of moderate mitral regurgitation. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Mikati determined in audit, and Ms. Rhodes does not adequately dispute, that her level of regurgitation was based on measurements that overestimated claimant's mitral regurgitant jet area by improperly characterizing black pixels and backflow as mitral regurgitation. Similarly, Dr. Abramson concluded, and claimant did not dispute, that the LAA tracing on claimant's echocardiogram excludes some of the left atrium and that the two largest RJA tracings included black pixels outside the true mitral regurgitation envelope. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of the claim of Ms. Rhodes for Matrix Benefits and the related derivative claim submitted by her spouse.